



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,014	02/09/2001	Olexander Hnojewj	1849.16102-A CIP 3	7416
26308	7590	12/22/2003		
RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			EXAMINER RUSSEL, JEFFREY E	
			ART UNIT 1654	PAPER NUMBER

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/780,014

Applicant(s)

HNOJEWYJ, OLEXANDER

Examiner

Jeffrey E. Russel

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☒ Claim(s) 44-46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1654

1. The Sequence Listing filed September 16, 2003 is approved.
2. The disclosure is objected to because of the following informalities: The status of the parent applications in the claim for priority at page 1 of the specification should be updated. There is no part of Figure 1 which is labeled "16" as indicated at page 4, line 28, of the specification. At page 15, line 20, "Lyophilization" is misspelled. At page 17, line 5, "reversible" should be changed to "reversibly". There is no part of Figure 2 which is labeled "42" as indicated at page 22, line 27, and page 23, line 4. Page 27, line 18, of the specification refers to a "Fig. 8"; however, only six figures were filed with the application. Appropriate correction is required.
3. Claims 2, 6-13, 16, 18, and 22 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 2, the absence of Markush terminology plus the use of "and" at line 5 implies that each one of the named polymers must be simultaneously present in the first component. It is not clear that this is what was intended by Applicant, i.e. it may be that the claim should be amended so that the polymers are alternatives to one another. Claim 6 recites a "material according to claim 1"; however, claim 1 is drawn to a composition, not a material. Claim terminology needs to be standardized in order to avoid issues of antecedent basis. For analogous reasons, claims 8-13 and 22 are indefinite for their use of the term "material". Claim 9 is indefinite because the language "selected from a group consisting essentially of" is improper Markush language. Because of the word "essentially", it is no longer clear if the scope of the claim is limited to those members of the group recited in the claim. For analogous reasons, the Markush language in claims 11, 12, 16, and 18 is indefinite. Claim 16 is

Art Unit: 1654

indefinite because "serum" and "serum fractions" are not the names of proteins. Claim 18 is indefinite because the meaning of the language "selected from a group consisting essentially of comprising" is unknown. Claim 18 is indefinite because chitosan and hyaluronic acid are polysaccharides, not proteins. Claim 22 is indefinite because it is not clear in what the concentration of the HSA is to be measured. It is not clear if the claim is reciting, e.g., the concentration of the HSA in the hydrophilic protein, the concentration of the HSA in a solution which comprises the second component, or the concentration of HSA when mixed with the first component.

4. Claims 26, 27, 29, and 30 are objected to because of the following informalities: At claim 26, line 7, and claim 29, line 8, "buffer" should be changed to "buffered". Appropriate correction is required.

5. Claim 18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 18 recites chitosan and hyaluronic acid, which are not proteins and are not embraced within the scope of claim 17, which requires a hydrophilic protein.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1654

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-16, 21, and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 6,458,147.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '147 patent anticipate instant claims 1-6, 8-16, 21, and 22. Note that an intended use limitation, i.e. "for sealing a vascular puncture site", does not impart patentability to product claims where the product is otherwise anticipated by the prior art. With respect to instant claim 7, it would have been obvious to one of ordinary skill in the art to optimize pHs within the pH range claimed in the '147 patent because pH is an art-recognized result effective variable which is routinely determined in the chemical arts.

8. Claims 1-7, 10, 12-16, 21, and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,371,975. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '975 patent anticipate instant claims 1-6, 10, 12, 13-16, 21, and 22. With respect to instant claim 7, it would have been obvious to one of ordinary skill in the art to optimize pHs within the pH range claimed in the '975 patent because pH is an art-recognized result effective variable which is routinely determined in the chemical arts.

9. Claims 1-7, 14-16, and 20-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/212,472. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '472 application anticipate

Art Unit: 1654

instant claims 1, 2, 5-7, 14-16, and 20-24. An assembly/apparatus comprising a composition anticipates claims drawn to the composition, and an intended use limitation does not impart patentability to product claims which are otherwise anticipated by or obvious over the prior art. With respect to instant claims 3, 4, and 25-32, although the '472 application does not claim a PEG molecular weight or the weight ratios of the components in the liquid closure material, It would have been obvious to one of ordinary skill in the art to determine all operable and optimal PEG molecular weights and component ratios in the liquid closure material claimed in the '472 application, because molecular weight and reactant ratios are art-recognized result-effective variables which are routinely determined and optimized in the polymer arts. With respect to instant claims 33-39, it would have been obvious to one of ordinary skill in the art to package the claimed assembly of the '472 application with instructions for use because it is routine in the pharmaceutical arts to package active agents in kit form including instructions for use, because this improves the ease of storage, transportation, measurement, and administration. With respect to the actual text of the instructions for use, such text does not impart patentability to claims drawn to the kit/assembly/apparatus.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-16, 21, and 22 are directed to an invention not patentably distinct from claims 1-41 of commonly assigned U.S. Patent No. 6,458,147. See the above obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Art Unit: 1654

Commonly assigned U.S. Patent No. 6,458,147, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

11. Claims 1-7, 10, 12-16, 21, and 22 are directed to an invention not patentably distinct from claims 1-9 of commonly assigned U.S. Patent No. 6,371,975. See the above obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned U.S. Patent No. 6,371,975, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the

Art Unit: 1654

conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

12. Claims 1-7, 14-16, and 20-39 are directed to an invention not patentably distinct from claims 1-34 of commonly assigned U.S. application 10/212,472. Specifically, see the above provisional obviousness-type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned U.S. application 10/212,472, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly

Art Unit: 1654

assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

13. The effective filing date of instant claims 1-46 is deemed to be February 9, 2001, the filing date of the instant application. Claims 1-46 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 09/283,535 because the '535 application, under the test of 35 U.S.C. 112, first paragraph, does not disclose sealing a vascular puncture site; does not disclose a second component comprising a nucleophilic material in general; does not disclose an electrophilic polymer material with a degradation control region where the electrophilic polymer material is other than PEG; does not disclose an oxycarbonylimidazole cross-linking group; does not disclose second components/hydrophilic proteins which are hybrid proteins or which comprise at least one synthetic amino acid sequence; does not disclose a buffer material which includes tris-hydroxymethylaminomethane; and does not disclose the particular numerical ratios recited in instant claims 26, 27, 29, and 30.

Because U.S. Patent Nos. 6,458,147 and 6,371,975 have earlier effective filing dates and different inventorships than the instant application, they are available as prior art against the instant claims under 35 U.S.C. 102(e).

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1654

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

15. Claims 1-6, 8-18, 21, 22, and 33-36 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,458,147. See the above obviousness-type double patenting rejection. In addition, the '147 patent teaches second components/hydrophilic proteins which are water soluble derivatives of hydrophobic proteins, e.g., collagen, elastin, chitosan, and hyaluronic acid, and teaches the compositions in kit form with instructions for use. See, e.g., column 4, lines 28-30, and column 10, lines 8-15. Although the instructions taught by the '147 patent will not discuss sealing a vascular puncture site, the content of the instructions can not be relied upon to impart patentability to a product or apparatus claim where the product or apparatus is otherwise anticipated by the prior art.

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,458,147. See the above obviousness-type double patenting rejection.

17. Claims 1-6, 8-18, 21, 22, 33-36, and 40-43 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,371,975. See the above obviousness-type double patenting

Art Unit: 1654

rejection. In addition, the '975 patent teaches the cross-linking groups of instant claims 8-13; teaches second components/hydrophilic proteins which are water soluble derivatives of hydrophobic proteins, e.g., collagen, elastin, chitosan, and hyaluronic acid; teaches the compositions in kit form with instructions for use; and teaches using the compositions to seal a vascular puncture site. See, e.g., column 3, lines 6-7; column 9, lines 12-19; column 11, lines 17-31; and column 14, lines 26-28.

18. Claim 7 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,371,975. See the above obviousness-type double patenting rejection.

19. Claims 1-6, 8-16, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhee et al (U.S. Patent No. 5,874,500). Rhee et al teach a composition comprising tri- or tetra-functionally activated PEG in PBS and tetra-amino PEG in PBS. The PEG in the tetra-functionally activated PEG has a molecular weight of 10,000. Upon mixing, an elastic gel is formed. See, e.g., Example 3. The tri- or tetra-functionally activated PEG corresponds to Applicant's first component which has an active ester/N-hydroxysuccinimide cross-linking group, and the tetra-amino PEG corresponds to Applicant's second component which has an amine cross-linking group. PBS has a pH of about 7.4. In general, Rhee et al teach that cross-linking groups can include those which react with thiols and amines, such as aldehydes, vinyl sulfones, and orthopyridyl disulfide; teach that a biodegradable group can be included between the polymer and the linking group to increase degradation of the crosslinked polymer composition in vivo; and teach polylysine, collagen, gelatin, albumin, fibrin, and fibrinogen as preferred polymers comprising multiple nucleophilic groups. See, e.g., column 4, lines 39-55; column 5, lines 23-44; column 6, lines 46-61; and column 11, line 35 - column 13, line 33. The

Art Unit: 1654

compositions can be used as a biosealant to seal fissures or crevices within a tissue or structure such as a vessel. See column 20, lines 15-17. The biodegradable group of Rhee et al corresponds to Applicant's degradation control region. With respect to the claim limitation "for sealing a vascular puncture site", an intended use limitation does not impart patentability to product claims where the product is otherwise anticipated by or obvious over the prior art.

20. Claims 33-35 are rejected under 35 U.S.C. 103(a) as being obvious over Rhee et al (U.S. Patent No. 5,874,500). Application of Rhee et al is the same as in the above rejection of claims 1-6, 8-16, and 20. Rhee et al do not teach a kit with instructions for mixing the components and applying the mixture to seal a vascular puncture site. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to package the composition of Rhee et al in kit form with instructions for use because it is routine in the pharmaceutical arts to package active agents in kit for including instructions for use for ease of storage, transportation, measurement, and administration. With respect to the actual text of the instructions for use, such text does not impart patentability to claims drawn to the kit/system/apparatus.

21. Claims 40-42 are rejected under 35 U.S.C. 103(a) being obvious over Rhee et al (U.S. Patent No. 5,874,500) as applied against claims 1-6, 8-16, and 20 above, and further in view of Edwards et al (U.S. Patent No. 6,302,898). Rhee et al teach using their composition to seal fissures or crevices within a tissue or structure such as a vessel (see column 20, lines 15-17), but does not specifically teach using their composition to seal vascular puncture sites. Edwards et al teach sealing vascular puncture sites by administering first and second fluent compositions which mix and form a nonfluent closure composition. See, e.g., claim 27. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use the

Art Unit: 1654

composition of Rhee et al to seal the vascular puncture sites, because Edwards et al teach the desirability of sealing vascular puncture sites using two fluent compositions which mix and form a nonfluent closure composition, because Rhee et al teach compositions having the same functions required by Edwards et al and which are used to seal similar defects, and because the compositions of Rhee et al have the benefits of providing a high compression strength and high swellability, easy injectability, the ability to covalently bind to primary amino groups on lysine residues of collagen molecules at the tissue site of administration and thereby anchoring the composition to the host tissue, non-immunogenicity, and resistance to enzymatic cleavage by matrix metalloproteinases (see column 3, lines 36-58).

22. Claims 1-6, 8-22, 33-36, and 40-43 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 09/520,856 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application. The '856 application teaches compositions used to seal vascular puncture sites. The compositions comprise the same electrophilic polymer material, nucleophilic material, and buffer claimed by Applicant. See, e.g., pages 20-21, species 1; and originally-filed claims 44 and 83-108.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the

Art Unit: 1654

filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

23. Claims 44-46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or suggest a method of sealing a vascular puncture site using a composition comprising an electrophilic polymer material having a functionality of at least three, human serum albumin, and a buffer material including tris-hydroxymethylaminomethane.

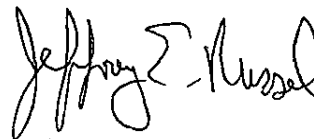
Doi et al (U.S. Patent No. 4,839,345) has been carefully considered but is not deemed to teach or suggest the instant claimed invention because Doi et al do not teach or suggest the use of a buffer during the crosslinking reaction. Note, for example, that Doi et al do not describe the pH of any of their components or reaction mixtures, and therefore do not provide any motivation to include a buffer in order to achieve any particular pH.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

PLEASE NOTE: Sometime on or around January 6, 2004, the examiner will be moving to the new USPTO headquarters. At that time, the examiner's phone number will change to (571) 272-0969. After January 6, it is recommended that Applicants attempt to contact the examiner at the new phone number if they are unable to reach him using the old number.

Art Unit: 1654

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Technology Center 1600 for formal communications is (703) 872-9306; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1600 receptionist is (703) 308-0196.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

December 16, 2003